K051054

JUN 29 2005

Section H

510(k) Summary for VisuLize™ Factor IX Antigen Kit (Summary of Safety and Effectiveness)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted By:

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Summary Prepared:

April 25, 2005

Name of the Device:

VisuLize™ Factor IX Antigen Kit
Common Name: Factor IX ELISA assay

Classification of Device:

Class II
21 CFR 864.7290, Factor Deficiency Test
Subpart H, Hematology Kits and Packages
Product Code: GGP

Predicate Device:

Asserachrom IX:AG, K854312
Diagnostica Stago (formerly American Bioproducts)

Device Description:

The VisuLize™ Factor IX Antigen kit is a sandwich enzyme-linked immuno-sorbent assay (ELISA) using a polyclonal antibody coated 96-microwell format. Plasma samples are diluted and applied to the pre-coated wells. After washing away unbound proteins, a horseradish peroxidase (HRP) labelled polyclonal antibody is applied to detect the captured Factor IX. A chromogenic substrate (TMB containing H_2O_2) is added to allow for color development. The color formed is measured spectrophotometrically at 450 nm, with the absorbance being directly proportional to the concentration of Factor IX that was in the sample.

Device Intended Use:

The VisuLize™ Factor IX Antigen Kit is an Enzyme Immunoassay for the quantitative determination of Factor IX Antigen in human plasma samples and Factor IX concentrates using the double antibody enzyme linked immuno-sorbent assay (ELISA).

Comparison to Predicate Device:

A technical comparison of the proposed device and the predicate device is illustrated in the following table:

	VisuLize™ Factor IX Antigen Kit (Proposed Device)	Asserachrom IX:AG Kit (Predicate Device)
Assay Principle	Quantitative determination of Factor IX antigen by sandwich ELISA (polyclonal – polyclonal HRP)	Quantitative determination of Factor IX antigen by sandwich ELISA (polyclonal – polyclonal HRP)
Intended Use	An enzyme immunoassay for the quantitative determination of Factor IX antigen in human plasma samples and Factor IX concentrates using the double antibody enzyme linked immuno-sorbent assay (ELISA).	An enzyme immunoassay (EIA) procedure for the quantitative determination of Factor IX by the sandwich technique also known as enzyme-linked immunosorbent assay (ELISA).
Sample Matrix	Human plasma derived from blood collected into 3.2% buffered citrate	Human plasma derived from blood collected into 3.2% buffered citrate
Intra-assay precision (CV%)	3.24% – 8.78%	5.31% – 5.84%
Inter-assay precision (CV%)	2.96% - 6.84%	5.99% - 6.39%
Linearity	Log-log curve, $R^2 \geq 0.990$	Log-log graph
Detection Limit	0.005 IU/mL (0.5%)	1%
Traceability of Calibrator Plasma	Calibrator plasma is standardized against a secondary standard that is traceable to the WHO International Standard for Factor IX Activity 99/826	Calibrator plasma is standardized against a secondary standard that is traceable to the WHO International Standard for Factor IX Activity 99/826

Clinical Performance Comparison:
The clinical performance of the VisuLize™ Factor IX Antigen Kit versus the Asserachrom IX:AG kit was compared to demonstrate substantial equivalence. Testing of clinical samples across the entire detection range was conducted internally and by two external testing sites. The results obtained by the three testing sites demonstrated excellent correlations between the proposed and predicate devices, as illustrated in the following table:

Summary of all Clinical Data from 3 Testing Sites

	INTERNAL TESTING	EXTERNAL TESTING SITE #1	EXTERNAL TESTING SITE #2
Number of Samples	134	114	109
Pearson Product Moment correlation co-efficient (r)	0.987	0.976	0.982
P-value (Single factor ANOVA)	0.528	0.458	0.228

Conclusion: Based on the technical comparison and clinical performance results, it is concluded that the VisuLize™ Factor IX Antigen kit is substantially equivalent to the Asserachrom IX:AG enzyme immunoassay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 29 2005

Ms. Denise Foulon
Scientific Director
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Re: k051054
Trade/Device Name: VisuLize™ Factor IX Antigen Kit
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: II
Product Code: GGP
Dated: April 25, 2005
Received: April 26, 2005

Dear Ms. Foulon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K051054

Device Name: VisuLize™ Factor IX Antigen Kit

Indications for Use:

The VisuLize™ Factor IX Antigen Kit is intended for use as an *in vitro* diagnostic assay for the quantitative determination of Factor IX antigen in human plasma samples and Factor IX concentrates using the double antibody enzyme linked immuno-sorbent assay (ELISA).

Prescription Use _____ **AND/OR** Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K051054